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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,932	12/10/2003	Chetan P. Pujara	7262US01	6677

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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,932	PUJARA, CHETAN P.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/10/03, 2/20/04 and 5/13/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, drawn to a powder for oral suspension comprising cefdinir, classified in class 514, subclass 193, for example.

II. Claims 23-24, drawn to a method of treating bacterial otitis media, pharyngitis, and tonsilitis with an oral suspension of cefdinir, classified in class 514, subclass 193, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for usin the product can be practiced with another materially different product. For example acute bacterial otitis and pharyngitis can be treated with a composition comprising penicillin or other antibiotic compound.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination

purposes as indicated is proper. It is noted that while the searches of Groups I and II may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group I, the Examiner will be focusing on the patentability of the product itself, and not the process of using of Group II. Conversely, in searching Group II, the Examiner will be focusing on the patentability of the process and not the product itself. Accordingly, a search for both groups would pose an undue burden on the Office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Michael Ward on April 20, 2006, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-22. Affirmation of this election must be made by applicant in replying to this

Office action. Claims 23-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DETAILED ACTION

Claims 1-24 are pending in the application, with claims 23-24 having been withdrawn as drawn to a non-elected invention. Accordingly, claims 1-23 are being examined on the merits herein.

The claims are being rejected as follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the FDA Approved label for OMNICEF® (cefdinir), approved on July 14, 1999, in view of the article entitled "New Cephalosporins" to Sheldon L. Kaplan, 2001, Seminars in Pediatric Infectious Disease, Volume 12, No. 3, pages 169-174.

The OMNICEF® (cefdinir) label discloses that the medication is available in a form that can be reconstituted for oral suspension (i.e. powder form) (see page 1 of approved label insert, in particular.) The label discloses that the form for oral suspension contains, after reconstitution, 125 mg cefdinir per 5 mL, and also contains inactive ingredients such as sucrose, citric acid, sodium citrate, sodium benzoate, and others (see page 1 of approved label insert, in particular.)

The OMNICEF® (cefdinir) label insert does not specifically teach that the powder form for reconstitution contains greater than 4.2% by weight of cefdinir, or 6-10% by weight cefdinir, as in claim 2, or at least 8.4% cefdinir, as in claims 3-4 .

Kaplan teaches that oral suspensions of cefdinir are effective against various types of gram-positive and gram-negative organisms (see page 172 and Table 2, in particular.) Kaplan teaches that different concentrations of cefdinir can be used according to the type of organism being targeted (see Table 2, in particular), and teaches various dosages of the cefdinir that have been approved for the treatment of various conditions, such as 14 m/kg/day for the treatment of streptococcal pharyngitis/tonsilitis (see page 172, left hand column, in particular.) Kaplan also teaches that studies have shown that once-daily dosing of cefdinir is better than a regimen of 2 divided doses for pneumococcal AOM in children, or acute bacterial sinusitis in adults (see page 173, right hand column, in particular.) Thus, Kaplan

teaches that the dosage of cefdinir can be selected according to the type of bacteria, desired dosing regimen (i.e. once a day vs. twice a day), and condition to be treated.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of cefdinir provided in the powder for oral suspension as taught by the OMNICEF® label insert, according to the guidance provided by Kaplan, for example to achieve an amount of cefdinir in the composition of greater than 4.2% by weight, or even at least about 8% by weight, with the expectation of providing a composition having desired treatment properties, such as a desired efficacy against a specific type of bacterial, desired treatment of a specific bacterial infection and/or a desired treatment regimen and/or frequency. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, the powder for oral suspensions as recited in claims 1-3 are considered to be obvious over the OMNICEF® (cefdinir) label insert in view of the teachings of Kaplan.

Regarding claims 4-8, it is noted that the OMNICEF® (cefdinir) label insert discloses that the composition contains sucrose (a diluent), as in claims 4-6, and a combination of citric acid and sodium citrate (buffering agents), as recited in claims 7-8.

Claims 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the FDA Approved label for OMNICEF® (cefdinir), approved on July 14, 1999, in view of the article entitled "New Cephalosporins" to Sheldon L. Kaplan, 2001, Seminars in Pediatric Infectious Disease, Volume 12, No. 3, pages 169-174, as applied to claims 1-8 above, and further in view of U.S. Patent No. 5,112,604 to Beaurline et al, issued May 12, 1992, U.S. Patent Application Publication No. 2002/0146455 to Kundu et al, and U.S. Patent No. 5,460,828 to Santus et al, issued October 24, 1995.

The OMNICEF® (cefdinir) package label and Kaplan are applied as discussed above, and render obvious providing a powder for oral suspension comprising cefdinir in an amount of about 8.4%, as in claim 9, or 8.36%, as in claim 22. It is furthermore noted that the OMNICEF® (cefdinir) package label teaches that the composition for oral suspension further comprises sucrose (a diluent), citric acid and sodium citrate (a buffering agent), sodium benzoate (a preservative), xanthan gum and guar gum (viscosity enhancing agents), artificial strawberry and cream flavors (flavoring agent), silicon dioxide (glidant) and magnesium stearate (lubricant), and thus teaches including the components (a)-(h) as recited in claim 9, the components as recited in claims 10-21, and components (a)-(h) and (j) of claim 22.

Regarding the amount of the flavoring agent provided, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the artificial strawberry and cream flavors

provided in the composition, according to the guidance provided by the package label and Kaplan, to provide a composition having desired properties, such as desired strawberry and/or cream flavor and/or desired intensity of flavor. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

The references do not teach providing the other components in the specific amounts as recited in claim 9 and 22, and also do not specifically teach that the silicon dioxide is provided in the form of colloidal silicon dioxide, as recited in claim 22.

Beaurline et al. teaches aqueous suspensions for oral administration of drugs (see abstract, in particular.) Beaurline et al. teaches that such suspensions can contain preservatives such as sodium benzoate to preserve the composition (see column 2, lines 57-65, in particular.) Beaurline et al. also teaches that colloidal silicon dioxide and a hydrocolloid gum, such as guar gum and xanthan gum, can be used to aid in suspension of pharmaceutical agents in the composition (see column 1, lines 40-65 and column 2, lines 5-40, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the sodium benzoate preservative provided in the OMNICEF composition, according to

the preservative guidance provided by Beaurline et al, with the expectation of providing a composition having desired stability and preservative properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide colloidal silicon dioxide as the silicon dioxide form in the composition of OMNICEF® and Kaplan, because OMNICEF® and Kaplan teach the composition can be used for forming an oral suspension, and can contain silicon dioxide, and Beaurline et al. teaches that it is known to provide colloidal silicon dioxide to act as a suspending agent in suspension compositions. Thus, one of ordinary skill in the art would have been motivated to provide the colloidal silicon dioxide with the expectation of providing a suitable suspending agent for the composition. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the colloidal silicon oxide and/or xantham gum and guar gum provided in the OMNICEF® and Kaplan composition, according to the suspending aid guidance provided by Beaurline et al, with the expectation of providing a composition having desired suspension properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

The OMNICEF® (cefdinir) package label, Kaplan and Beaurline et al, do not specifically teach providing the recited amounts of citric acid and sodium citrate (buffering agent), sucrose (diluent) and/or magnesium stearate (lubricant), as recited in claims 9 and 22.

Kundu et al. teaches the preparation of aqueous pharmaceutical suspensions for oral delivery (see abstract, in particular.) Kundu et al. teaches that it is know to provide pH modifiers or buffer to maintain a final pH of the composition, such as a pH that gives good stability, and also teaches that such buffers can include citric acid and sodium citrate (see paragraph 0036, in particular.) Kundu et al. also teaches that it is know to provide sweeteners in suspensions, such as sucrose, to act as taste-masking agents (see paragraph 0032, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the citric acid and/or sodium citrate buffer provided in the OMNICEF®, Kaplan and Beaurline et al. composition, according to the buffering guidance provided by Kundu et al, with the expectation of providing a composition having desired properties, such as desired pH and stability of the composition. It is noted that "[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the sucrose sweetener provided in the OMNICEF®, Kaplan and Beaurline et al. composition, according to the sweetener guidance provided by Kundu et al, with the expectation of providing a composition having desired properties, such as desired sweetness and taste-masking properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

The OMNICEF®, Kaplan, Beaurline et al, and Kundu et al. references do not specifically teach providing the magnesium stearate (lubricant) in the amounts as recited in claims 9 and 22.

Santus et al. teaches a composition having microgranules that can be used in pharmaceutical liquid suspension formulations (see abstract, in particular.) Santus et al. teaches that the microgranules for the suspensions can include other excipients that are

commonly used in pharmaceuticals, such as lubricants including magnesium stearate (see column 5, lines 15-30, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the magnesium stearate lubricant provided in the OMNICEF®, Kaplan, Beaurline et al, and Kundu et al. composition, according to the lubricant guidance provided by Santus et al, with the expectation of providing a composition having desired properties, such as desired lubricant properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Thus, claims 9-22 are considered to be obvious over the teachings of the OMNICEF® package label, in view of Kaplan, and further in view of Beaurline et al, Kundu et al. and Santus et al.

Conclusion

No claims are allowed.

The prior art being made of record and not relied upon that is considered pertinent to applicant's disclosure is listed in the accompanying PTO-892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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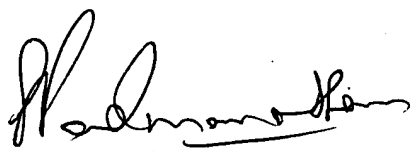

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